EVALUATION OF A NEW PULP CAPPING AGENT: A CLINICAL INVESTIGATION

by
Ronald Francis Nirschl

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TABLE OF CONTENTS

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

LIST OF ILLUSTRATIONS

INTRODUCTION

Indirect pulp therapy has been demonstrated to be a reliable method of conservative pulp therapy clinically, radiographically, and histologically.

Particularly, calcium hydroxide-based materials have been shown to be effective medicaments in indirect pulp therapy.

As more proprietary formulae of calcium hydroxide bases are developed and changes are made in formulae, it is the responsibility of the dental profession to test these materials for continued clinical reliability.

This study compared clinical results of indirect pulp therapy in human teeth when Improved Dycal and an experimental calcium hydroxide formula produced by the L. D. Caulk Company were used as the therapeutic bases.

Clinical signs and symptoms, direct visual examinations and radiographic examinations were used to evaluate the clinical results.

REVIEW OF LITERATURE

Historical background (1746-1950)

Ripp[1] reports that Fauchard, as early as 1746, recognized the value of conservative treatment of extensively carious teeth. Fauchard recommended retention of some caries if its complete removal would cause a pulp exposure, realizing that the alternative would be removal of the tooth if the pulp were exposed. Little mention of this conservative approach appeared again until the 1850's.

Tomes[2] in 1859 cited a presentation by Foster in New York City, during which Foster recommended the use of Hill's stopping as a temporary filling material in extensively decayed teeth. Foster allowed some carious dentin to remain in the teeth. After placing the Hill's stopping, he would not re-enter the cavity for at least five months. After this treatment period, Foster's criterion for success was the ability to condense a gold filling into the cavity. Both men recognized the danger of condensing gold over an unsound dentinal base. Tomes stated that only softened or decomposed tissue should be removed, leaving the discolored dentin to protect the pulp. Black[3] strongly opposed leaving any carious material in the cavity preparation.

According to Miller,[4] practitioners generally recognized a need for cavity sterilization, realizing that traces of softened dentin remaining in the preparation could contain cariogenic organisms. Miller stated in 1891 that if all infected dentin is not removed, thorough sterilization must form the basis of conservative treatment. He compared the relative sterilization properties of several agents and recommended that medicaments be used for an extended time, preferably overnight. He warned of potential injury to pulps of teeth which are exposed or nearly so. Among the agents that Miller found most acceptable were trichloride of iodine, bichloride of mercury, and hydrogen peroxide.

One other agent recognized to be an effective germicide and to have rapid penetrating properties in dentin was oil of cloves. In 1899 Williams[5] outlined a treatment using alcohol and oil of cloves to cleanse the cavity preparation. He recognized the importance of the inflammatory condition of the pulp for the prognosis of the tooth, and stated that leaving carious dentin was acceptable only if there was little inflammation of the pulp.

In 1900 Inglis[6] compared decalcified dentin to decalcified bone and recognized the acid content of decalcified dentin. He proposed recalcification of the dentin as a means of pulpal protection. He also stated that decalcification precedes penetration of the dentin by microorganisms and asked his contemporaries to test his axiom clinically.

In 1906 Miller[7] studied the action of silver nitrate in conservative pulp treatment. On pieces of ivory he demonstrated a marked protective action, but reported complete failure in a few cases. He came to no conclusions as to how silver nitrate worked, but was confident that no adverse pulp reaction was induced during the short duration of silver nitrate application. Howe[8] proposed that silver nitrate was effective through silver reduction in which silver from $AgNO_3$ in formic acid solution permeates softened dentin, but not sound tissue; this reaction leaves a heavy deposit of metallic silver. Howe emphasized the ability of silver nitrate to sterilize dentin while being very tolerable by other oral tissue.

While studying the relationship of deep caries to pulp involvement, Best[9] was impressed with the need for refining one's diagnostic evaluation of teeth prior to pulp therapy and emphasized a meticulous aseptic technique. For improved results, Best's[10] recommendations included avoidance of pulp exposures, recognizing a higher rate of success in non-exposed teeth. He suggested leaving the treatment base for six to twelve months, depending upon the depth and extent of the cavity. In 1928 Grove[11] reinforced Best's concern for proper diagnosis and technique. Recognizing that this treatment did not assure permanent results, Grove discussed the cell processes in wound healing and recommended further studies in the area to develop more successful pulp treatments. In the same year Fish[12] studied the reaction of dentin to injury. He observed that pulpal changes begin as soon as dentin is affected by caries. Dentinal tubules exposed to injury change to "dead tracts" and the pulp immediately begins to lay down secondary dentin as a protective barrier. In 1930 Hermann[13] introduced a calcium hydroxide material for use in pulpotomies.

Coolidge[14] stated in 1932 that control of caries depended upon the removal of softened dentin and hermetic sealing of the cavity more than upon the medicament used. He noted that most American practitioners in the early 1930's were using zinc oxide or calcium phosphate and he voiced concern regarding the use of eugenol, formaldehyde, zinc chloride, phenol, or other caustic agents which might destroy the vitality of the pulp. He recognized that pulp therapy at the time was based almost solely upon clinical experience, not experimental evidence.

Bodecker[15] studied the correlation between caries and the histologic condition of the pulp, to determine the benefits of temporary fillings. He noted that immediate placement of permanent filling material could cause extensive formation of secondary dentin. Removal of only the soft dentin and placement of temporary oxyphosphate cement or zinc oxide-eugenol were recommended when caries closely approximated the pulp. The tissue reaction observed by Bodecker was a slow build-up of secondary dentin, which he interpreted to be more nearly a normal response.

In 1936 Prime[16] recommended the use of silver nitrate solution, citing three properties of particular value: (1) it is readily diffusible in dentin; (2) it cleaves toxic products of protein decomposition; and (3) it has an ability to neutralize the acid of caries. In 1939 Ireland[17] confirmed caries arrest in primary teeth using ammonical silver nitrate. A year later Heine[18] reviewed techniques and materials used in pulp capping and concluded that the silver nitrate solution introduced by Howe[8] remained as the best treatment available unless the decay had already reached the pulp tissue. Numerous other authors, including Barker,[19] Easlick,[20] Ogur,[21] and Zander,[22] supported this view. Seltzer[23] reinforced this view in 1940, when he demonstrated the presence of bacteria in the dentin of teeth prepared for restorations. He noted that the chances of leaving microorganisms increased with increasing depth of the cavity.

In 1934 Hess[24] examined histologic results of direct and indirect capping with zinc oxide-eugenol agents. He determined that healthy exposed pulp could be assisted to recovery by direct capping and demonstrated similarly favorable results in indirect pulp therapy.

Zander[25] proposed in 1940 that any material containing easily ionized calcium or phosphate placed in contact with pulp tissue would cause precipitation or laying down of calcium salts and proposed this as the probable action of calcium hydroxide. In deciduous and permanent teeth with pulp exposures, he demonstrated that calcium hydroxide used as a direct capping agent provided favorable results without inflammation. A dentinal bridge lined by odontoblasts was shown to develop, both in healthy and inflamed pulps.

In 1940 Prime[26] modified the treatment he recommended. While continuing initially with silver nitrate application, after a couple of days he would seal the cavity with a zinc oxide-eugenol filling to be left in place as long as six months, citing a need for time to allow the tooth to heal by formation of sclerotic dentin.

Muntz, Dorfman, and Stephan[27,28] discussed the rationale for germicide application and correlated it to histologic studies of bacterial invasion of the cavities. They divided the cavity into layers. The superficial layer was always infected, the intermediate layer was sometimes infected, and the partially decalcified dentin adjacent to sound dentin and sound dentin were almost always sterile. In the same year Besic[29] questioned the need for sterilization after studying the fate of microorganisms sealed into cavities. He found viable organisms as late as one and one-half years after placing restorations, but noted no gross indications of decay progression. Similar findings were reported by Kraus.[30] Besic, however, continued to recommend the use of sterilizing agents in deep cavities. Orban,[31] on the other hand, felt that the few bacteria left in dentinal tubules would be destroyed by pulp tissue defenses.

In 1943 Zander and Burrill[32] questioned the ability of silver nitrate to penetrate to the depths of bacterial invasion, particularly in the short period of its application. Muntz, Dorfman and Stephan[27] demonstrated a 0.25 to 0.50 mm penetration of silver nitrate into decayed dentin with a three-minute application and 0.75 mm penetration after ten minutes.

In 1949 Glass and Zander[33] compared healing of exposed pulps treated with calcium hydroxide and zinc oxide-eugenol cements. They showed no healing in pulps capped with zinc oxide-eugenol. These pulps remained viable with a chronic inflammatory reaction at the exposure site. Teeth treated with calcium hydroxide rapidly healed free of inflammation. After studying the effects of calcium hydroxide on the pulp, Berk[34] in 1950 stated that calcium hydroxide paste had all the desirable properties for pulp treatment with none of the undesirable properties of agents previously used. He recommended its use for pulp capping in teeth with healthy pulps.

The carious lesion in dentin

Yoshida and Massler[35] described dentinal caries as having three zones: (1) necrotic dentin, a thick, very soft layer saturated with bacteria, not painful upon removal; (2) another soft layer, but containing few bacteria; (3) an innermost layer of hard, but discolored dentin. Both of the inner layers are painful upon removal. Other studies have shown that dentinal demineralization precedes bacterial invasion of dentin.[36-39] Massler[40] differentiated between affected and infected dentin. The primary organisms found in the infected dentin are cocci and gram positive bacilli.[29,38,41] Langeland[42] showed that dentin affected by caries is permeable and does not prevent penetration to the pulp of drugs, bacteria, or their irritating products. In teeth whose pulps are actively depositing reparative dentin in advance of decay, another layer exists which is normal, unaffected dentin, but softer than the overlying carious dentin.[38]

Injury to the dentin in the form of caries stimulates sclerosis of primary dentin[43] and deposition by the pulp of reparative dentin.[12,44,45] Carious exposure of the pulp occurs when the tooth is unable to deposit reparative dentin with a speed and quantity to stay in advance of the decay.[43] The structure and width of the reparative dentin are related to the intensity and duration of the stimulus, the condition of the pulp,[38] and the thickness of the overlying primary dentin.[46,47] These reactions appear to be reactions to bacterial toxins which transcend the dentinal tubules in advance of the bacteria.[36] The elaboration of reparative dentin decreases the pulp's future ability to defend itself.[43] The reparative dentin is more atypical in structure during rapid deposition; it is the superficial layer, while the pulpal layers of reparative dentin are more regular.[46]

The persistence of dental caries provides a continuous stimulus for an inflammatory response to occur within the pulp,[43] the extent of this reaction being proportional to the extent of decay.[42] Langeland[42] said that pulpal changes begin long before bacteria approach the pulp. Shovelton[48] quantified this and found that caries must be within 0.80 to 1.10 mm of the pulp before any disturbance within the pulp is apparent and must approach within 0.30 to 0.50 mm of the pulp before any significant inflammation can be observed. Similar results were reported by Reeves and Stanley.[49] Irreversible pulp damage does not occur until dentinal caries reaches advanced stages.[37] The inflammation is a defense response. Low grade irritation stimulates production of reparative dentin; however, once irritation surpasses an unknown threshold, degenerative changes of the pulp occur.[50] When the caries progresses at a more rapid rate than the reparative dentin, the blood vessels dilate and scatter cells of the chronic inflammatory type, while the pulp reacts to a site of carious exposure with an acute inflammatory response.[43] The response of deciduous pulp to caries is similar to that which occurs in permanent teeth, but involvement restricted to the coronal pulp of primary teeth is rare. This is probably because the lesions of primary teeth are most commonly interproximal lesions, which anatomically approximate radicular pulp.[51] Additionally, Langeland[42] showed that pulpal reaction is not equally distributed throughout the pulp, but is localized to areas nearest the caries.

Bacterial penetration of the pulp is a late stage of advanced caries.[37,49,52] Pain is not necessarily indicative of pulpal penetration by microorganisms.[37,43] The pain experienced is usually of dentinal, not pulpal, origin.[52] When pulpal infection does occur, the organisms are pyogenic streptococci, pyogenic staphylococci, and gas-forming bacilli.[40] Work with germ-free rats demonstrates clearly the importance of bacterial contamination as a factor influencing the response of exposed pulps.[53-55] In germ-free animals, Kakehashi, Stanley and Fitzgerald[53,54] demonstrated the healing of untreated exposed pulps with little evidence of pulpal inflammation or necrosis.

The layer of residual dentin remaining in indirect pulp therapy is usually contaminated with microorganisms.[41,56,57] When these cavities are sealed with only an amalgam restoration and later reopened, cultures of viable microorganisms persist.[41,57,58] Some authors[58,59] feel that no further progression of decay occurs, while others are uncertain of the microorganisms' ability to produce cariogenic acids.[60] Under calcium hydroxide or zinc oxide-eugenol bases, the number of viable organisms is greatly reduced.[41,56] Aponte[56] showed a 93 percent reduction of cultivable cavities after four years in teeth lined with calcium hydroxide. Similarly, King[41] showed a 61 percent reduction in teeth treated with a calcium hydroxide base and an 82 percent reduction in teeth treated with zinc oxide-eugenol bases after 25 to 206 days.

Indirect pulp therapy technique

Numerous authors have outlined the techniques employed in indirect pulp therapy.[41,46,61-64] Basically, they consist of removal of all carious dentin except that which, if removed, would cause exposure of the pulp, and placement of a treatment dressing to stimulate deposition of reparative dentin by the pulp. Calcium hydroxide and zinc oxide-eugenol dressings are commonly used. Another base is generally placed over the therapeutic base and then the cavity is sealed, often with amalgam. After an appropriate interval for healing, the dressing and remaining carious dentin are removed and the tooth is appropriately restored. Delaney and Seyler[65] used a hardset calcium hydroxide material as a sole base and placed the final restoration immediately. They reported favorable results based on clinical and radiographic evidence. Ability to resist intrusion of amalgam upon condensation has been demonstrated with hard-setting bases used as the sole base material.[66,67]

While some authors advocate removal of only the superficial, necrotic dentin,[68] others recommend removing all infected dentin.[40]

Still others make judgments relative to the amount of dentin left covering the pulp and recommend that from 1.00 mm[69] to 3.00 mm[70] should remain. Some authors suggest use of local anesthetic,[41,62] while others advocate excavation without anesthesia and removal of only the non-painful dentin.[64,68]

Removing the superficial layer of cariogenic bacteria arrests the carious process and results in pulpal recovery in the majority of teeth.[56,71] A marked reduction of inflammation occurs when all carious dentin is removed, even without placement of a treatment dressing.[42] Langeland[42] warns that some drugs may actually increase the inflammatory response at this time.

Reparative dentin forms slowly, approximately 1.50 microns per day or 0.10 mm every three months.[72] Law and Lewis[73] observed a radiopaque area forming on the pulpal side of residual caries as early as seven days. Most authors recommend waiting from six weeks[43] up to as long as six months[74] before re-entering the cavity. The two-visit technique is generally accepted;[63,75] however, a one-visit technique has been reported.[65]

Unintentional pulp exposures, microscopic in size, may occur,[76-78] as experimentally demonstrated by Marzouk and Van Huysen.[79] Microorganisms may inadvertently be forced into the pulp chamber upon such exposure. Exposure of the pulp significantly worsens the prognosis.[74] Additionally, a good temporary seal is necessary for favorable results.[80,81]

Criteria for selection of teeth treated with indirect pulp therapy have been established. Jordan,[82] who had a 93 percent success rate with indirect pulp therapy, states that high rates of success depend upon careful pre-operative evaluation. Specifically, he recommends an evaluation of pulp vitality, using history of pain and radiographic appearance as aids. A posterior bitewing radiograph helps to evaluate pulpal involvement with caries, while a periapical radiograph allows examination of periapical and bifurcation regions for possible pathosis.[83] Presence of calcific masses in the pulp chamber is suggestive of advanced pulpal involvement and contraindicates indirect pulp therapy.[50] Error may exist in the practitioner's ability to accurately determine the proximity of caries to the pulp;[84] however, it is advisable to anticipate that the caries will extend deeper than radiographically evidenced.[83] Dimaggio and Hawes[74] showed that 75 percent of teeth selected for indirect pulp therapy would have had pulpal exposures if all caries had been removed.

While some authors feel that pain is not a good indication of pulpal status,[85] its occurrence may be helpful in evaluation for indirect pulp therapy.[43,50,86] A history of spontaneous pain or pain at night often indicates extensive pulpitis,[50,86] whereas pain or sensitivity while eating may be due to gingival irritation or chemical irritation of the pulp through the thin dentinal cover.[50] Complete absence of toothache does not guarantee pulpal health, as pulp degeneration may occur without pain.[50] Thermal and electrical pulp testing have not been proven to be accurate.[43,83,86]

Other clinical signs and symptoms which contraindicate indirect pulp therapy include pain with percussion, intra- or extra-oral swelling, or abnormal tooth mobility.[43,50] Guthrie, McDonald and Mitchell[86] showed no clear relationship between hemograms and the extent of pulp pathosis. They used the first drop of blood following intentional exposures of the pulp. However, some degree of relationship between the hemogram with an elevated neutrophil count was recorded in teeth with extensive pulpal inflammation.

Massler[40] states that optimal healing should include: (1) an amount of reparative dentin at the pulpal end equaling the amount of dentin lost from the dentoenamel junction; (2) formation of regular, tubular dentin rather than irregular dentin or osteodentin; and (3) presence of a slight inflammatory reaction which leads to healing rather than a severe, chronic destruction of the pulp.

Following calcium hydroxide application, radiographic increase in mineralization of underlying dentin may be observed.[73,87,88] Clinically, this dentin has been shown to be harder than primary dentin.[56,89] Sayegh[90,91] has shown that more reparative dentin will form after indirect pulp therapy than after direct pulp capping. This response was seen in primary and secondary teeth, in single and multiple rooted teeth, and in teeth with or without complete root development. The greatest amount of reparative dentin is produced when the thinnest layer of carious dentin remains in the preparation.[90]

Medicaments in indirect pulp therapy

Ripp[1] states that the ideal drug in pulp capping would be bland and non-irritating to the pulp while stimulating growth of new dentin and allowing the pulp to heal. Caustic drugs which destroy dentinal cells and peripheral odontoblasts are contraindicated. Silver nitrate is one such drug.[92] The two most widely accepted drugs for indirect pulp therapy are calcium hydroxide and zinc oxide-eugenol.

The mode of calcium hydroxide action is not fully understood.[72,93] Its bacteriostatic and bactericidal action,[47,94,95] together with its alkalinity, may play a role in arresting the carious process.[47,93,95,96] Tronstad[93] demonstrated an increase in pH of saline subjected to calcium hydroxide bases. The mineral content of softened dentin can be increased by applying calcium hydroxide.[47,73,88,97] It is believed that this is a result of exchange of minerals from the pulp.[47,98-100]

Lewis and Law[73] described the histologic condition of a pulp twelve months after indirect pulp therapy with calcium hydroxide. The occlusal dentin was decalcified and contained numerous microorganisms. Secondary dentin and predentin had formed on the pulpal surface adjacent to decalcified dentin and there was a definite zone of Weil with active odontoblasts. Other authors have noted a little inflammatory response associated with calcium hydroxide application.[61,101] Since microscopic exposure of the pulp may go undetected, response of the exposed pulp to the capping agent is important. Berk[34,102] described healing of the exposed pulp which occurs by organization of a blood clot with fibroblastic activity, resulting in the formation of a protective callus of organic collagenous tissue. Calcification of this tissue was noted. Others have demonstrated the formation of new dentin in regions of exposed vital pulps.[13,97,103,104] Additionally, increased calcification of primary dentin occurs in adjacent areas.[97,105] Calcium hydroxide also serves to protect the pulp from chemical irritation.[106,107]

Undesirable responses to calcium hydroxide have been reported. Internal resorption and complete calcification of root canals have been observed following indirect pulp therapy with calcium hydroxide.[1,108,109]

However, McWalter, El-Kafrawy, and Mitchell[110] contend that calcium hydroxide compounds applied to exposed pulps do not exert a persistent stimulating effect on reparative dentin which would lead to eventual pulp obliteration.

Zinc oxide-eugenol materials are also used as bases in indirect pulp therapy. Some authors report no significant difference between teeth without pulp exposures treated with calcium hydroxide and zinc oxide-eugenol bases.[101,111-113] Others report better response of the pulp with less chronic inflammation when calcium hydroxide is applied.[114] Zinc oxide-eugenol bases have been found to be an irritant by virtue of their free eugenol content.[115] When zinc oxide-eugenol has been placed close to the pulp, chronic inflammation and necrosis have been reported.[116-119] Ehrenreich[120] reports that only zinc oxide-eugenol bases are effective in rehardening carious dentin.

Other materials have also been tested for indirect pulp therapy. Recent studies indicate that applying stannous fluoride significantly increases hardening of residual dentin when compared with calcium hydroxide.[121] Additionally, application of other substances including corticosteroid-antibiotic combinations,[96,116,122,123] polycarboxylate cement,[124] and isobutlycyanoacrylate[125,126] have been suggested, but to date, none has shown results to justify their use.[116,125,126]

Prognosis in indirect pulp therapy

The prognosis of a tooth treated with indirect pulp therapy is favorable,[56,74,82,89] and better than the prognosis with direct pulp capping or pulpotomy under similar circumstances.[127,128] A range of success rates has been reported for indirect pulp therapy. Law and

Lewis[73] report that 76 percent of primary and permanent teeth treated with calcium hydroxide indirect pulp therapy were clinically and radiographically sound after two years. Kerkhove[89,112] reports 85 percent to 93 percent success after twelve months in a study using calcium hydroxide and zinc oxide-eugenol, while Dimaggio and Hawes[74] report 99 percent favorable results with the same agents. Looking at specific criteria, Damele[129] reports that 90 percent of teeth treated with calcium hydroxide showed increased radiopacity adjacent to the pulp and Mehlum[130] has demonstrated that 80 percent of teeth similarly treated had reparative dentin formation after three months. Jordan[82] reports a 98 percent success rate using a reinforced zinc oxide-eugenol material.

Histologic evaluation of 41 permanent teeth treated with calcium hydroxide over 34 to 630 days revealed that clinical signs of pulpitis occurred in only four teeth. All but one of the teeth retained vitality and 60 percent showed essentially normal pulp tissue without inflammation.[46] DeSouza, Holland and Hysatugu[131] compared radiographic examination to histologic condition of pulps treated with conservative pulp therapy and found approximately a 75 percent correlation between radiographic diagnosis and histologic examination.

Sowden[88] in 1956 stated that the degree of success of pulp treatment depends upon the ability of the practitioner to make careful evaluation of treatable and untreatable teeth. Massler[40] feels that:

> A review of the literature suggests that previously held erroneous ideas concerning failure in pulpal healing were based on experimental methods and clinical procedures which today would be regarded as inadequate and/or destructive.

Schroeder[122] warns that decline of clinical symptoms does not imply a simultaneous regeneration from a histologic perspective, while Berk[61] feels that success can often be determined from radiographs which show increased density of the dentin or additional secondary dentin formation. Hawes and Dimaggio[128] state that success rates determined clinically and radiographically are higher than those determined histologically.

METHODS AND MATERIALS

Selection of teeth

The teeth treated in the study were randomly selected from the Pedodontic Department at Indiana University School of Dentistry. After an initial determination of radiographic evidence of a deep carious lesion approaching the pulp (Figure 1), each tooth was selected only after fulfilling the following criteria:

1. No history of spontaneous, unprovoked toothache. The tooth may have had a history of toothaches associated with eating, as long as pain subsided immediately after removal of the stimulus.
2. No radiographic evidence of periapical pathology.
3. No valid tenderness to percussion.
4. No abnormal mobility.
5. No evidence of abnormal internal or external root resorption.[132]

The sample included 38 teeth including 14 deciduous first molars, 16 deciduous second molars, six permanent first molars, and two permanent second molars. All teeth selected were judged to be teeth that would normally be retained for at least one year beyond the date of treatment. The control group consisted of 18 teeth treated with the commercially available Improved Dycal, while 20 teeth were treated with the experimental paste. Four teeth were removed from the original sample, leaving a control group of 16 teeth and an experimental group of 18 teeth.

Operative procedure

The teeth were treated under local anesthetic, and isolated for treatment with rubber dam. Conventional cavity preparations were made using a number 330 carbide bur. Caries was removed with a number 6 or number 8 round bur in a slow speed handpiece and/or a small spoon excavator. All carious dentin was removed except that which, if removed, might have caused exposure of the pulp, in the operator's opinion. Cavity preparations were then cleansed and dried using an air-water syringe and tap water.

Teeth were randomly selected for application of therapeutic bases using a coded number system. Both experimental and control bases were applied in teeth of mouths which contained more than one treatable tooth; however, selection of the material for individual teeth was random.

The therapeutic bases served as the sole base material. It was covered with an application of Copelite* varnish and restored using amalgam restorations for the temporary seal.

Immediate post-operative radiographs were taken using the Rinn BAI film holding instrument** modified to allow duplication of focal length (Figures 2 and 3). A bitewing radiograph and a periapical radiograph were taken of each tooth and Kvp, Ma and focal length settings were recorded for later reference to aid in reproducing consistent post-operative radiographs.

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*Copelite, Cooley and Cooley LTD, Houston, Texas.

**Rinn BAI film holding instrument, Rinn Corporation, Elgin, Illinois.

Three-month evaluation

Patients were recalled at the end of three months and the teeth were evaluated clinically and radiographically. Bitewing and periapical radiographs were taken of each tooth using the modified Rinn apparatus. The parents and patients were questioned regarding any history of toothache in the treated teeth. The teeth were examined to determine that the restorations were intact, that the teeth were not abnormally mobile, and that pain was not evoked upon percussion. Radiographs were examined for radicular or bifurcation pathology, abnormal root resorption, and for evidence of change in the area of remaining carious dentin.

Six-month evaluation

At the end of six months, patients were again recalled. This recall was arranged so that patients were seen within two weeks either side of the actual six-month anniversary. Clinical and radiographic evaluations were completed as at the three-month interval. Additionally, teeth were anesthetized, isolated with rubber dam, and the amalgam restorations removed, while an attempt was made not to disturb the therapeutic base. The bases were examined to determine the physical characteristics of the material and then were removed with a small spoon excavator. Next, direct observation of remaining carious dentin was made. The color of the residual dentin was recorded at this time and a subjective estimate of its hardness was made. A sharp number 23 explorer was used to evaluate the soundness of the dentin. Any remaining unsound dentin was likewise removed with a spoon excavator and the amount of dentin removed was estimated. This estimated amount was recorded along with a notation as to whether removal of this dentin resulted in exposure of the pulp.

Teeth determined to have been successfully treated were restored with the appropriate bases and restorative materials. Teeth with pulp exposures were also appropriately treated with the indicated pulp therapy and stainless steel crown restorations.

RESULTS

The data collected upon evaluation of the treated teeth at three months suggested failure of one tooth (Table I). This tooth, treated in the experimental group, presented with a fractured restoration, radicular pathology of the mesial root, and slight sensitivity to percussion. No abnormal root resorption or mobility was evident, and the patient was unaware of pain or discomfort in this tooth at any time since its treatment.

The remaining 17 teeth of the experimental group demonstrated the following characteristics after three months. Restorations of the teeth were intact. No abnormal root resorption or radicular pathology was radiographically evident. Mobility of the teeth was normal. The individuals reported no sensitivity upon percussion and no history of pain since treatment (Figure 4).

In the control group, similar results were reported for the 18 teeth of the group after three months (Table II), with one tooth slight discomfort was elicited upon percussion; the same tooth was occasionally sensitive to cold. The other teeth were neither sensitive to percussion nor had been associated with pain from any stimulus since treatment. All teeth of the control group had intact restorations and normal mobility (Figure 5).

At the six-month evaluation, the following data were collected in the experimental group (Tables III and IV). The tooth which had shown radicular involvement and a fractured restoration at three months demonstrated no additional signs or symptoms of progression of degeneration. The patient reported that the tooth had not been sensitive to stimuli and it was not sensitive to percussion. Radiographic evaluation demonstrated no abnormal root resorption, but the radicular pathology was still evident. Mobility of this tooth was normal. Upon re-entry of the preparation, the residual dentin was very dark brown, almost black, soft and mush wet. More than 0.50 mm of residual decayed dentin was removed and the pulp was exposed.

The remaining 17 teeth in the experimental group were judged to have been successfully treated at six months, a success rate of 94.4 percent. They demonstrated the following characteristics. Restorations were intact and the teeth exhibited normal mobility. There was no radiographic evidence of abnormal root resorption or radicular pathology. No individuals reported sensitivity upon percussion or a history of pain since the teeth had initially been treated. Clinical examination of the re-entered preparations provided the following information. Thirteen teeth had residual dentin judged to be light brown in color while the remaining four teeth had dark brown residual dentin. This dentin was hard in 15 teeth and two teeth had soft residual layers of dentin. The unsound residual dentin removed was more than 0.50 mm deep in only seven teeth (Figure 6).

In the control group, one tooth was judged to be a failure upon exposure of the pulp when the residual dentin was removed (Tables V and VI). This tooth exhibited the following characteristics. The restoration was intact and mobility was normal. The patient had experienced no pain since the previous evaluation and the tooth was not sensitive to percussion. There was no radiographic evidence of radicular pathology or abnormal root resorption. The residual dentin was light brown, soft and dry. More than a half millimeter of residual dentin was removed. The pulp was exposed upon evaluation of reparative dentin with a sickle explorer. Upon removal of coronal pulp, the root pulp stumps bled minimally. The pulp was subsequently treated with a five-minute formocresol pulpotomy.

The remaining 15 teeth in the control group were determined to have been successfully treated by the indirect pulp therapy, a success rate of 93.75 percent. One of these teeth was not re-entered as it supported a lingual arch and removal of the restoration would have necessitated construction of a new lingual arch. Clinically, this tooth demonstrated an intact restoration. No pain or sensitivity to percussion was reported and the tooth radiographically was normal. The other 14 teeth in the control group had restorations intact at the six-month evaluation and demonstrated normal mobility. None of these teeth had any signs of radicular pathology or abnormal root resorption. These teeth had been free of pain and were not sensitive to percussion. Re-entry of these 14 teeth in the control group resulted in no exposures. In all cases, the residual dentin was dry; it was dark brown in five teeth and light brown in nine. Twelve teeth had hard residual dentin and in only two was the residual dentin somewhat soft. Only a superficial amount of unsound dentin remained in nine teeth and five had more than one-half millimeter of unsound dentin remaining over sound dentin (Figure 7).

Statistical analysis was completed on three variables: success rate, strength of residual dentin, and amount of residual dentin remaining over sound dentin. The analysis was computed in two ways. First, the data was analyzed with Chi Square and secondly, analysis was made with

Chi Square using the Yates correction formula. The Yates formula is used with small cell frequencies for a more conservative test of statistical significance. Between the experimental and control groups on the success rate of the indirect pulp therapy the Chi Square analysis yields a value of 0.007, and a value of 0.415 with the Yates correction. Neither of these is significant at the 0.05 level since a Chi Square of 3.841 is required with one degree of freedom. Comparison of successful pulp therapy to strength of residual dentin yields a Chi Square of 9.580 which is statistically significant at the 0.01 level since a value of 6.635 is required with one degree of freedom. With the Yates correction the Chi Square value is 4.620 which is statistically significant at the 0.05 level. Neither the Chi Square analysis with a value of 2.889 nor the Chi Square with the Yates correction factor with a value of 0.925 shows statistical significance for the amount of residual dentin removed following pulp therapy (Table VII).

TABLES AND FIGURES

Figure 1: Periapical and bitewing pre-operative radiographs of tooth #30 demonstrating a typical carious lesion selected for the study.

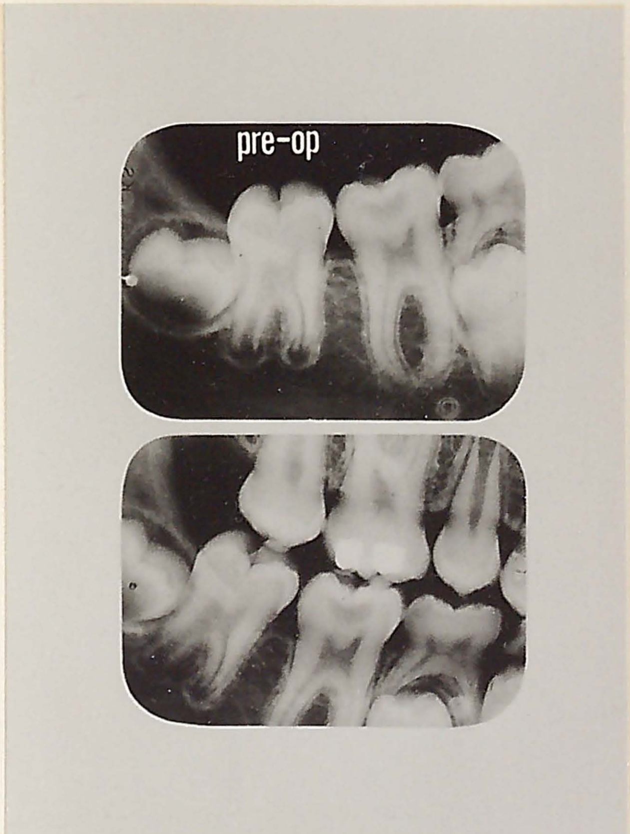
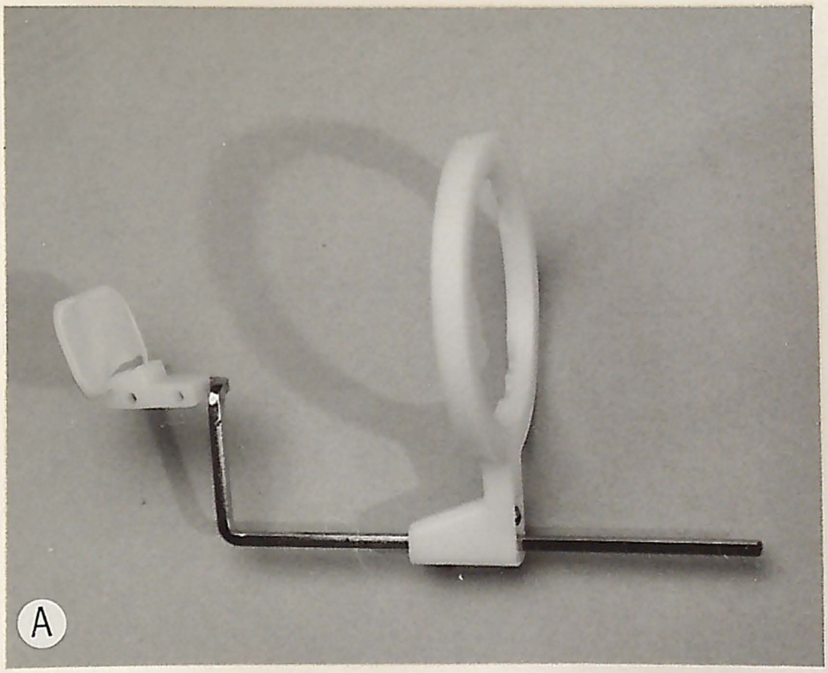

pre-op

Figure 2: The Rinn BAI film holding instruments used for serial radiographs.

a. Periapical film holder

b. Bitewing film holder


A

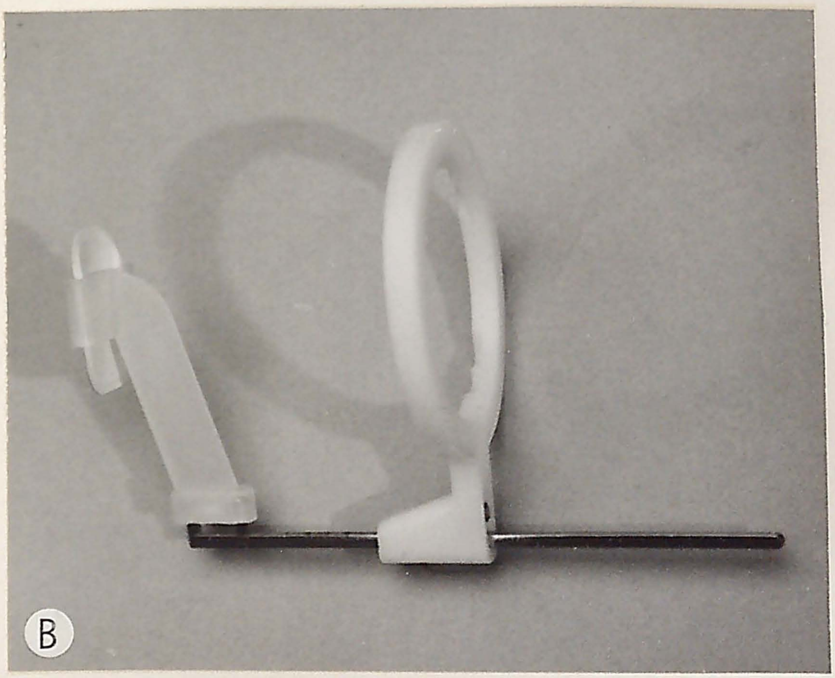

B

Figure 3: Clinical use of the bitewing film holder demonstrated.

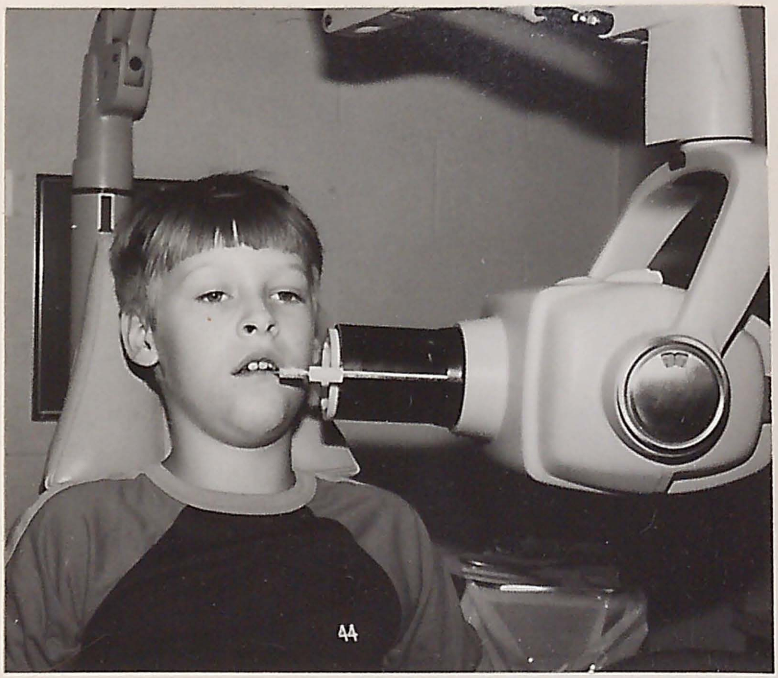

44

Figure 4: Immediate post-operative, three-month and six-month bitewing and periapical radiographs of tooth #L treated in the experimental group.

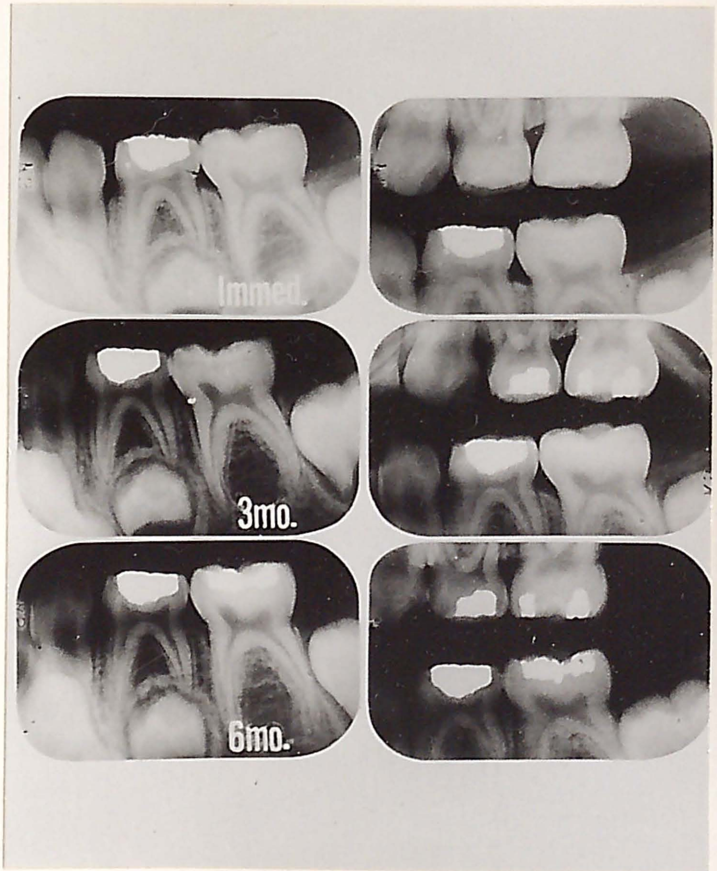

Immed.
3mo.
6mo.

Figure 5: Immediate post-operative and six-month bitewing and periapical radiographs of tooth #A treated in the control group.

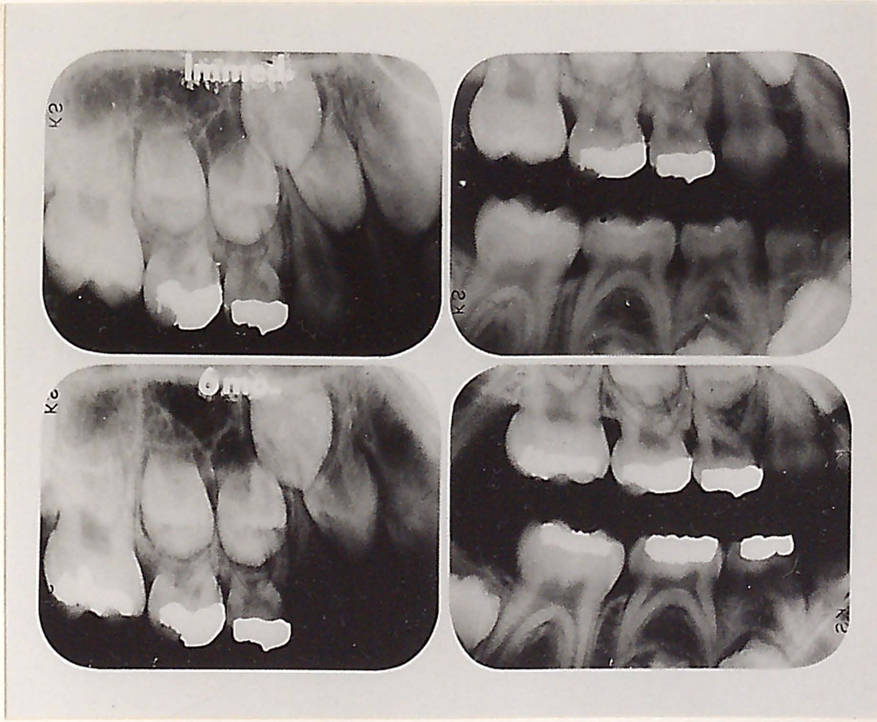

Immed.
6 mo.

Figure 6: Six-month clinical evaluation of tooth #L treated in the experimental group.

a. Restoration intact

b. Base material: intact, dry and firm

c. Residual dentin: light brown, dry and hard

d. Solid dentinal base

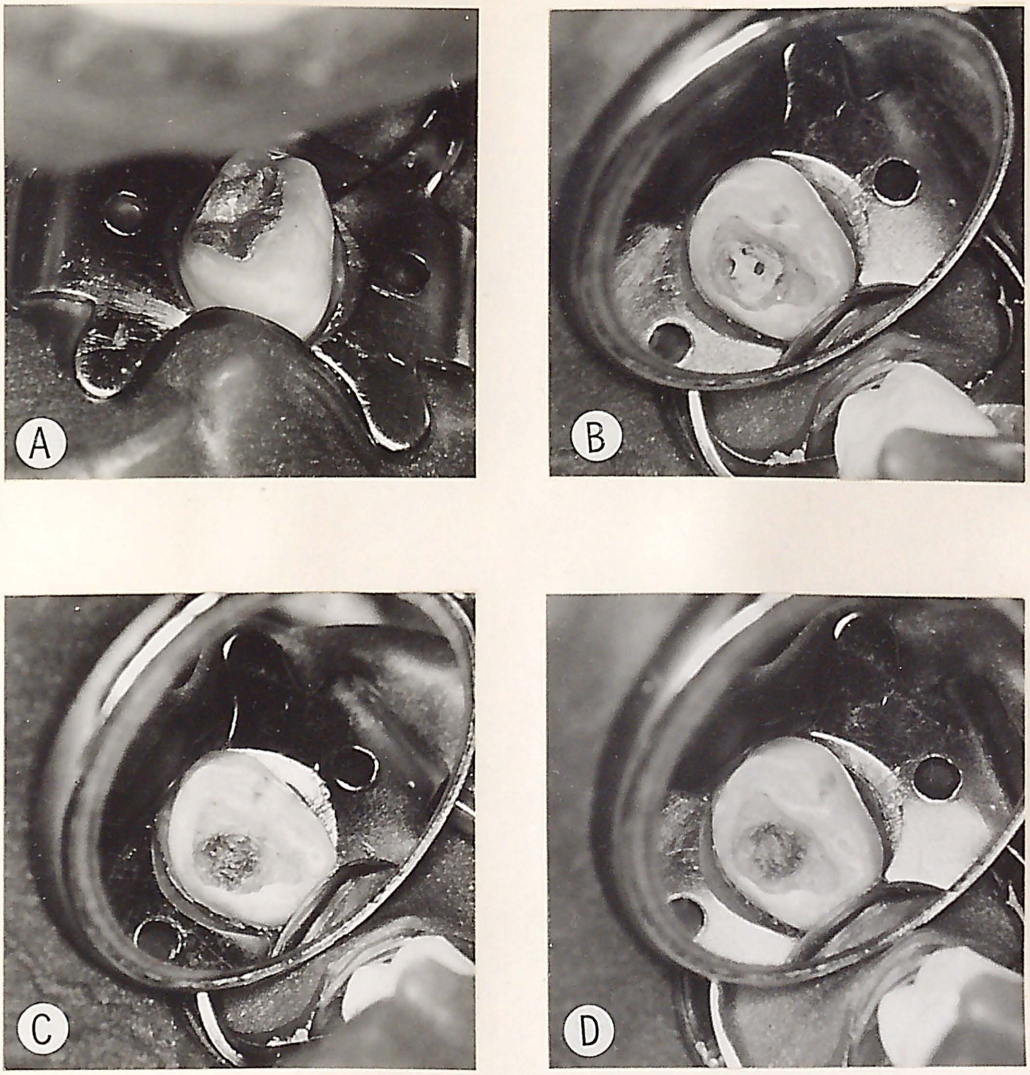
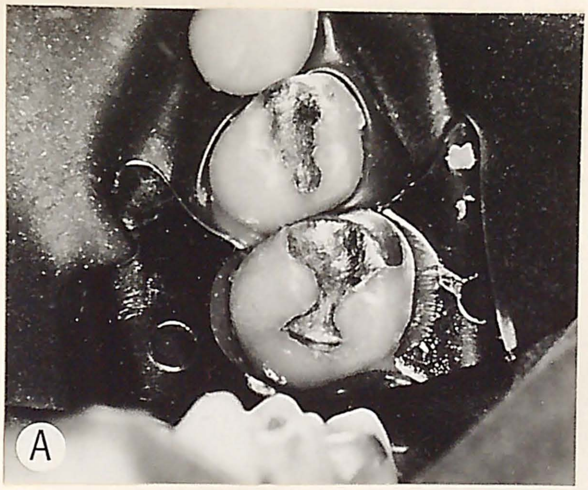

A
B
C
D

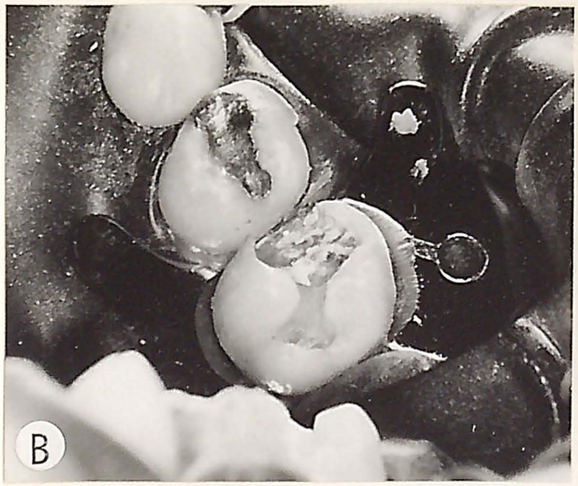
Figure 7: Six-month clinical evaluation of tooth #A treated in the control group.

a. Restoration intact

b. Base material: intact, dry and firm

c. Residual dentin: light brown, dry and hard


A


B


C

TABLE I

Three-Month Evaluation
Experimental Group

Tooth Number	Restoration Intact	Radicular Pathology	Abnormal Root Resorption	Sensitivity to Percussion	Mobility	Pain
14	YES	NO	NO	NO	Normal	NO
18	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
19	YES	NO	NO	NO	Normal	NO
31	YES	NO	NO	NO	Normal	NO
B*	---	---	---	---	---	---
B	YES	NO	NO	NO	Normal	NO
L	NO	Mesial Root	NO	Slight	Normal	NO
K*	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
J	YES	NO	NO	NO	Normal	NO
I	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO

*Removed from Sample

TABLE II

Three-Month Evaluation
Control Group

Tooth Number	Restoration Intact	Radicular Pathology	Abnormal Root Resorption	Sensitivity to Percussion	Mobility	Pain
3	YES	NO	NO	Slight	Normal	With Cold
30*	YES	YES	NO	YES	Normal	NO
30	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
A*	YES	NO	NO	NO	Normal	NO
19	YES	NO	NO	NO	Normal	NO
J	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
J	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO
S	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO

*Removed from Sample

TABLE III

Six-Month Clinical and Radiographic Evaluation
Experimental Group

Tooth Number	Restoration Intact	Radicular Pathology	Abnormal Root Resorption	Sensitivity to Percussion	Mobility	Pain
14	YES	NO	NO	NO	Normal	NO
18	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
19	YES	NO	NO	NO	Normal	NO
31	YES	NO	NO	NO	Normal	NO
B*	--	--	--	--	--	--
B	YES	NO	NO	NO	Normal	NO
L	NO	Mesial Root	NO	NO	Normal	NO
K*	--	--	--	--	--	--
L	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
J	YES	NO	NO	NO	Normal	NO
I	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO

*Removed from Sample

TABLE IV

Six-Month Evaluation of Residual Dentin
Experimental Group

Tooth Number	Color of Residual Dentin	Strength of Residual Dentin	Moisture of Residual Dentin	Amount of Residual Dentin	Exposure of Pulp
14	Light Brown	Soft	Dry	>0.5 mm	NO
18	Light Brown	Soft	Dry	>0.5 mm	NO
K	Light Brown	Hard	Dry	<0.5 mm	NO
19	Dark Brown	Hard	Dry	>0.5 mm	NO
31	Light Brown	Hard	Dry	>0.5 mm	NO
B*	--	--	--	--	--
B	Light Brown	Hard	Dry	<0.5 mm	NO
L	Dark Brown	Soft	Wet	>0.5 mm	YES
K*	--	--	--	--	--
L	Dark Brown	Hard	Dry	<0.5 mm	NO
T	Light Brown	Hard	Dry	<0.5 mm	NO
A	Dark Brown	Hard	Dry	>0.5 mm	NO
A	Dark Brown	Hard	Dry	<0.5 mm	NO
J	Light Brown	Hard	Dry	<0.5 mm	NO
T	Light Brown	Hard	Dry	<0.5 mm	NO
K	Light Brown	Hard	Dry	>0.5 mm	NO
L	Light Brown	Hard	Dry	<0.5 mm	NO
B	Light Brown	Hard	Dry	>0.5 mm	NO
L	Light Brown	Hard	Dry	<0.5 mm	NO
T	Light Brown	Hard	Dry	<0.5 mm	NO

*Removed from Sample

TABLE V

Six-Month Clinical and Radiographic Evaluation
Control Group

Tooth Number	Restoration Intact	Radicular Pathology	Abnormal Root Resorption	Sensitivity to Percussion	Mobility	Pain
3	YES	NO	NO	NO	Normal	NO
30*	--	--	--	--	--	--
30	YES	NO	NO	NO	Normal	NO
T	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
A*	--	--	--	--	--	--
19	YES	NO	NO	NO	Normal	NO
J	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
K**	YES	NO	NO	NO	--	NO
J	YES	NO	NO	NO	Normal	NO
K	YES	NO	NO	NO	Normal	NO
A	YES	NO	NO	NO	Normal	NO
L	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO
S	YES	NO	NO	NO	Normal	NO
B	YES	NO	NO	NO	Normal	NO

*Removed from Sample
**Not Re-entered

TABLE VI

Six-Month Evaluation of Residual Dentin
Control Group

Tooth Number	Color of Residual Dentin	Strength of Residual Dentin	Moisture of Residual Dentin	Amount of Residual Dentin	Exposure of Pulp
3	Dark Brown	Hard	Dry	< 0.5 mm	NO
30*	--	--	--	--	--
30	Dark Brown	Hard	Dry	> 0.5 mm	NO
T	Dark Brown	Hard	Dry	< 0.5 mm	NO
K	Dark Brown	Hard	Dry	< 0.5 mm	NO
A	Light Brown	Hard	Dry	< 0.5 mm	NO
A*	--	--	--	--	--
19	Light Brown	Hard	Dry	> 0.5 mm	NO
J	Light Brown	Hard	Dry	< 0.5 mm	NO
L	Light Brown	Hard	Dry	< 0.5 mm	NO
K**	--	--	--	--	--
J	Light Brown	Hard	Dry	< 0.5 mm	NO
K	Light Brown	Hard	Dry	> 0.5 mm	NO
A	Dark Brown	Soft	Dry	> 0.5 mm	NO
L	Light Brown	Soft	Dry	< 0.5 mm	NO
B	Light Brown	Soft	Dry	> 0.5 mm	YES
S	Light Brown	Hard	Dry	> 0.5 mm	NO
B	Light Brown	Hard	Dry	< 0.5 mm	NO

*Removed from Sample
**Not Re-entered

TABLE VII

Chi Square Comparisons of Three Variables

(a) Success Rate

	Experimental	Control	Total
Successful	17	15	32
Unsuccessful	1	1	2
Total	18	16	34

$X^2 = 0.007$ (n.s.) X^2 (Yates correction)[1] $= 0.415$ (n.s.)

(b) Strength of Residual Dentin

	Hard	Soft	Total
Successful	27	4	31
Unsuccessful	0	2	2
Total	27	6	33

$X^2 = 9.580$** X^2 (Yates correction) $= 4.620$*

(c) Amount of Residual Dentin

	Superficial	$>1/2$ mm	Total
Successful	19	12	31
Unsuccessful	0	2	2
Total	19	14	33

$X^2 = 2.889$ (n.s.) X^2 (Yates correction)[1] $= 0.925$ (n.s.)

[1]Yates correction formula: $X^2 = \dfrac{N\left(\left|ad-bc\right| - \frac{N}{2}\right)^2}{(a+b)\ (a+c)\ (b+d)\ (c+d)}$

X^2 at 1df = 3.841 at 0.05*
6.635 at 0.01**
10.827 at 0.001

DISCUSSION

This study compared the clinical results obtained in indirect pulp therapy with two calcium hydroxide base materials. The teeth treated were evaluated on the basis of clinical signs and symptoms as well as radiographic evidence. The results confirm that a high rate of success can be anticipated when calcium hydroxide bases are used as the therapeutic base materials. This has previously been demonstrated by Lewis and Law,[73] Dimaggio and Hawes,[74] Kerkhove[89,112] and Damele.[129] Additionally, the study confirms acceptability of Dycal as a calcium hydroxide preparation, as previously demonstrated by Sawush,[133] McWalter, El-Kafrawy and Mitchell,[134] Tronstad,[135] Fisher,[136] and Eidelman.[47] The experimental calcium hydroxide material was not significantly different in clinical use from the currently available Improved Dycal. Both materials appeared to provide excellent bases for indirect pulp therapy under amalgam restorations.

No undesirable pulpal reactions were obvious from the current study and excessive pulp chamber calcification was not observed; however, histologic preparation of treated teeth is needed to verify these clinical observations for the experimental material.

Four teeth originally treated were removed from the sample. One tooth exfoliated prior to the three-month evaluation. Retrospective evaluation of this tooth gave no indication that it would exfoliate in such a short period. The therapy applied in this study, however, cannot be considered the cause because the contra-lateral tooth likewise exfoliated at this time. A second tooth received further treatment in a private practice. Neither parents nor the private practitioner was able to give any information which would aid in evaluation of the tooth. One patient moved away and was unavailable for follow-up evaluation. The final tooth removed from the study showed signs of pulpal degeneration and periapical involvement at the three-month evaluation. Retrospective evaluation of the initial radiograph of this tooth demonstrated periapical pathology previously undiagnosed.

The statistical analyses bear out the clinical findings. As expected there are no statistically significant differences between the experimental and control groups, nor between the group with superficial amounts of residual dentin and the group with more than one-half millimeter residual dentin. The two teeth treated unsuccessfully both had more than one-half millimeter residual dentin indicating that the amount remaining has some bearing on anticipated success of treatment. The results of this study show that more than one-half millimeter of residual dentin may be removed in successful treatment.

Between the groups with hard and soft residual dentin there is a statistically significant difference since none of the teeth with hard tissue failed, whereas half of those with soft residual tissue failed. Because of the small numbers of teeth in this study, one cannot make a definitive statement concerning the importance of strength of residual dentin in evaluating the prognosis.

No remarkable observations were made in teeth designated as successfully treated. The two teeth designated as failures had the following characteristics. One tooth had a fractured occlusal alloy restoration.

The underlying base material was soggy wet and soft. The residual dentin was also very wet and soft. It is assumed that leakage around the fractured restoration had penetrated to the cavity floor. The second tooth had no clinical signs or symptoms which would suggest unsuccessful treatment. This designation was based solely on exposure of the pulp, due to lack of solid dentin under the base material. The pulps of both teeth were vital upon entry to the chamber, bled minimally and appeared healthy in the investigator's estimation.

The base materials were observed to be hard and dry under all restorations after re-entry except the one under the fractured restoration. The materials appeared to have adequate strength to serve clinically as sole base materials in indirect pulp therapy under amalgam restorations.

The results of this study support observations made by El-Kafrawy[137] who compared pulp reactions to these two preparations and to conventional Dycal. In Macaca speciosa monkeys, El-Kafrawy demonstrated that each of these preparations is associated with pulp reactions that are comparable to those produced by conventional Dycal. These evaluations were made at intervals of 15, 45, and 90 days following direct pulp capping. An additional study is presently underway using the same base materials in direct pulp capping of human teeth. Data are minimal at this time because of lack of specimen teeth; however, preliminary results appear favorable.

SUMMARY AND CONCLUSIONS

This study compared clinical results of two calcium hydroxide bases used as the therapeutic bases in indirect pulp therapy in human teeth. Thirty-four teeth were randomly divided into two groups. The teeth were selected for indirect pulp therapy based on clinical and radiographic evaluation.

The teeth, isolated by rubber dam, were prepared under local anesthetic using conventional cavity preparation. A number 6 or number 8 round bur was used to remove all carious dentin except that which, if removed, was anticipated to expose the pulp. The calcium hydroxide bases were placed over residual carious dentin and an amalgam restoration was placed as a temporary seal.

The Rinn BAI film holding instruments were used to make radiographs. Immediate post-operative radiographs were taken the day of cavity preparation.

Patients were recalled after intervals of three and six months. The three-month evaluation consisted of clinical and radiographic examinations for signs and symptoms of pulp degeneration. At the six-month evaluation, in addition to the clinical and radiographic examinations, cavity preparations were re-entered and residual dentin was removed with a spoon excavator until a solid dentinal base was demonstrated.

High rates of successful indirect pulp therapy were achieved in both the control and the experimental groups. In the experimental group 94.4 percent of the teeth were judged successfully treated, while 93.75 percent of the teeth in the control group were judged to have been successfully treated after six months. Of the 34 teeth treated in the study, only two were demonstrated to be unsuccessful after six months. One of the two teeth experienced a fractured amalgam restoration and thus the seal against oral fluids was lost; the other tooth had no indication of unsuccessful treatment until the residual dentin was removed exposing the pulp.

Calcium hydroxide-based materials are effective agents for use in indirect pulp therapy. In this study, the commercially available Improved Dycal and an experimental preparation by the L. D. Caulk Company were shown to be effective calcium hydroxide bases. These hard-set calcium hydroxide bases may be used as the sole base material in indirect pulp therapy under amalgam restorations. An intact restoration providing a good seal seems essential for successful treatment.

Successful indirect pulp therapy can be predicted with a high degree of accuracy after six months using only clinical and radiographic evidence.

The results of this study seem to raise the following question. If post-operative signs and symptoms are favorable, is it necessary and/or desirable to re-enter teeth which have received indirect pulp therapy? A long-term study on deciduous teeth, followed through to exfoliation, with subsequent histologic examination could help to answer this question.

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VITAE

Ronald Francis Nirschl

February 19, 1950	Born in Toledo, Ohio
1968 - 1973	B.S.Ed., B.S. University of Cincinnati Cincinnati, Ohio
1973 - 1977	D.D.S. Ohio State University College of Dentistry Columbus, Ohio
1977 - 1979	Post-doctoral Pedodontic Graduate Program and Pedodontic Residency Indiana University School of Dentistry/ James Whitcomb Riley Hospital for Children Indianapolis, Indiana

Professional organizations

The American Dental Association
The American Society of Dentistry for Children

ABSTRACT

EVALUATION OF A NEW PULP CAPPING AGENT:

A CLINICAL INVESTIGATION

by

Ronald F. Nirschl

Indiana University School of Dentistry
Indianapolis, Indiana

This study compared clinical results of two calcium hydroxide bases used in indirect pulp therapy on human teeth.

Thirty-four teeth with deep carious lesions were treated with indirect pulp therapy. Eighteen teeth were treated with commercially available Improved Dycal and 16 teeth were treated with an experimental calcium hydroxide formula.

Evaluation was made at intervals of three and six months. After three months, periapical and bitewing radiographs were made and the teeth were examined clinically for signs of pulpal degeneration. At the six-month evaluation, in addition to the radiographic and clinical examinations, cavities were re-entered and the unsound residual dentin was removed to ascertain the presence of a solid dentinal base. Removal of all unsound residual dentin without an exposure of the pulp, as well as the clinical and radiographic examinations, were used to determine clinically successful treatment.

In the experimental group 15 teeth were successfully treated; a success rate of 94.4 percent. Seventeen teeth in the control group demonstrated successful indirect pulp therapy; a success rate of 93.75 percent.